U.S. FOOD & DRUG ADMINISTRATION

Keynote Address

Complete and Accurate Registration and Listing Data

Paul Loebach
Director, Drug Registration and Listing Staff

FDA U.S. FOOD & DRUG ADMINISTRATION

Agenda

1. *Why are we here, why are you here?*
2. *Sessions offered in today's workshop*
3. *Registration and Listing moving forward*

Why are we here, why are you here?

The Real Reason You're Here…

Section 510(b) of Food Drug and Cosmetic Act (FD&C)

During the period beginning October 1st and ending on December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs ... ***shall register*** *with the Secretary his name, places of business and all such establishments.*

Section 510(i) of FD&C

During the period beginning October 1st and ending on December 31 of each year, any establishments ***within any foreign country*** *engaged in the manufacture, preparation, ... of a drug that is imported or offered for import into the United States* ***shall ... register*** *with the Secretary the name and place of the establishment, the name of the United States agent for the establishment, the name of each importer of such drug that is known to the establishment*

Section 510(j) of the FD&C

Every person who registers with the Secretary ***shall file a list of all drugs*** *which are being manufactured, prepared, ...*

Section 502(o) of the FD&C

Misbranded if: "If it was manufactured, prepared,… ***in an establishment not duly registered*** *under section 510" or "if it was* ***not included in a list*** *required by section 510(j)"*

21 CFR 207 Code of Federal Regulations (see next slide)

Guidance for Industry: *Providing Regulatory Submissions in Electronic Format – Establishment Registration and Drug Listing* - Establishes Structured Product Labeling (SPL) as standard

Why are we here, why are you here?

The Real Reason You're Here…

Subpart A—GENERAL
§207.1 What definitions and interpretations of terms apply to this part?
§207.3 Bulk drug substance.
§207.5 What is the purpose of this part?
§207.9 Who does this part cover?
§207.13 Who is exempt from the registration and listing requirements?

Subpart B—REGISTRATION
§207.17 Who must register?
§207.21 When must initial registration information be provided?
§207.25 What information is required for registration?
§207.29 What are the requirements for reviewing and updating registration information?

Subpart C—NATIONAL DRUG CODE
§207.33 What is the National Drug Code (NDC), how is it assigned, and what are its requirements?
§207.35 What changes require a new NDC?
§207.37 What restrictions pertain to the use of the NDC?

Subpart D—LISTING
§207.41 Who must list drugs and what drugs must they list?
§207.45 When, after initial registration of an establishment, must drug listing information be submitted?
§207.49 What listing information must a registrant submit for a drug it manufactures?
§207.53 What listing information must a registrant submit for a drug that it repacks or relabels?
§207.54 What listing information must a registrant submit for a drug that it salvages?
§207.55 What additional drug listing information may FDA require?
§207.57 What information must registrants submit when updating listing information and when?

Subpart E—ELECTRONIC FORMAT FOR REGISTRATION AND LISTING
§207.61 How is registration and listing information provided to FDA?
§207.65 How can a waiver of the electronic submission requirement be obtained?

Subpart F—MISCELLANEOUS
§207.69 What are the requirements for an official contact and a United States agent?
§207.77 What legal status is conferred by registration and listing?
§207.81 What registration and listing information will FDA make available for public disclosure?

21 CFR 207

Why are we here, why are you here?

The Real Reason You're Here…

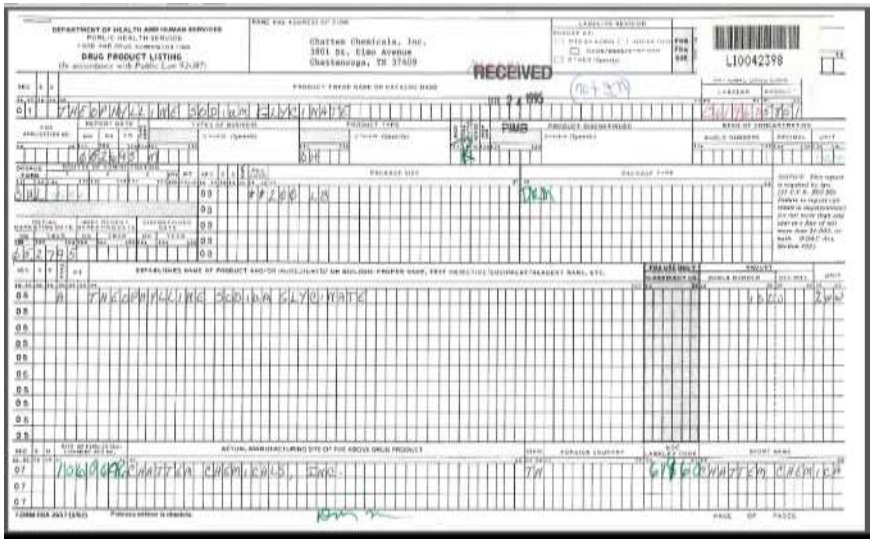
- Must do this annually!
  - Review and update ***all data*** (including contact information, US Agent and Importers)
  - ***Registration must be renewed between Oct 1st and Dec 31st*** to maintain current registration status
  - All registrations *automatically expire on Jan 1st if not renewed*. If you renew late, the registration record will show a gap in your registration status
  - Product listings *automatically expire on Jan 1st if not updated or certified.* A product listing may be updated any time during the year, or it may be certified between Oct 1st and Dec 31sr that no data has changed

FDA U.S. FOOD & DRUG ADMINISTRATION

Why are we here, why are you here?

In case you're longing for the good ol' days…

Form 2656 (later version)



Form 2657

Why are we here, why are you here?

DRLS Vision, Mission, and Values

Vision: ***A complete and accurate Drug Registration and Listing database***

Mission: *To enable industry to submit complete and accurate registration and listing data and to disseminate that data to those who need it.*

Values: *We are a customer service organization. To that end, it is far more efficient and beneficial to the FDA and Office of Compliance missions to spend an hour of time helping a company submit the data to us correctly, than to spend many hours seeking enforcement against those who do not.*

Our customers include:

Industry
Other FDA offices
Other government offices (Congress, CMS, DEA VA, etc.)
Healthcare providers
Academia
General public

We will be proactive and collaborative in assisting industry with submitting correct data, but firm in our commitment to ensuring compliance.

FDA U.S. FOOD & DRUG ADMINISTRATION

Why are we here, why are you here?

How we view the job we're doing…

Over 2000 registrants in person and on-line!

How you probably feel sometimes…

Why are we here, why are you here?

Recent important uses of DRLS data…

Recall of many “sartan” drugs due to potential presence of NDMA

DRLS used to help identify manufacturers of: Valsartan, Telmisartan, Irbesartan, Losartan, Olmesartan, Candesartan

Why are we here, why are you here?

Recent important uses of DRLS data…

Responses to natural disasters and other incidents

DRLS used to help identify manufacturers in affected areas from:

Hurricanes - Maria, Dorian

- Identify potential drug shortage situations

Fukushima nuclear plant explosion

- Identify contaminated products

FDA U.S. FOOD & DRUG ADMINISTRATION

Agenda

1. *Why are we here, why are you here?*
2. *Sessions offered in today's workshop*
3. *Registration and Listing moving forward*

Sessions Offered in Today's Workshop

Session 1: Registration and Labeler Code Requests

Presenters:
Lalnunpuii Huber and Donovan Duggan

D*U*N*S: 000111222

When and how do you register?

When and how can you get a labeler code?

Business operations and operation qualifiers

Updates to contact information

Sessions Offered in Today's Workshop

Session 2: NDC Reservation, Drug Listing, 503B Compounded Product Reporting

Presenters:
Troy Cu, David Mazyck, and Soo Jin Park

When and how to reserve an NDC, and does one need to be reserved first?

Drug listings: All the basics and what issues and errors to watch out for

503B Product Reporting: All the basics and what errors to watch out for

Sessions Offered in Today's Workshop

Session 3: Listing Certification and Inactivation

Presenters:
Regie Samuel and Leyla Rahjou Esfandiary

What is Certification?
Which products do I have to certify?
What happens if a product is not updated or certified?

Sessions Offered in Today's Workshop

Session 4: Compliance Program and Case Study

Tasneem Hussain and Julian Chun

What are the top errors DRLS sees?

What do we do when we find an error?
How do we notify you?
Will I get a warning letter?

Work assignment: Find and fix the problem!

Sessions Offered in Today's Workshop

Session 5: Town Hall Discussion

All Drug Registration and Listing Staff

We Want To Hear From You!

U.S. FOOD & DRUG ADMINISTRATION

Agenda

1. *Why are we here, why are you here?*
2. *Sessions offered in today's workshop*
3. *Registration and Listing moving forward*

Registration and Listing Moving Forward

Inactivation is Here!

As announced through the Federal Register in August 14, 2019:

The new annual certification requirement means that listings expire like establishment registrations and must be updated or renewed every year

Have already inactivated thousands of records. Some as old as 10 years!

Registration and Listing Moving Forward

A Revised Toolkit

We revised it to be more helpful with the technical side of R&L submissions

Registration and Listing Moving Forward

Future of the NDC

We're planning for the future,

So stay tuned…

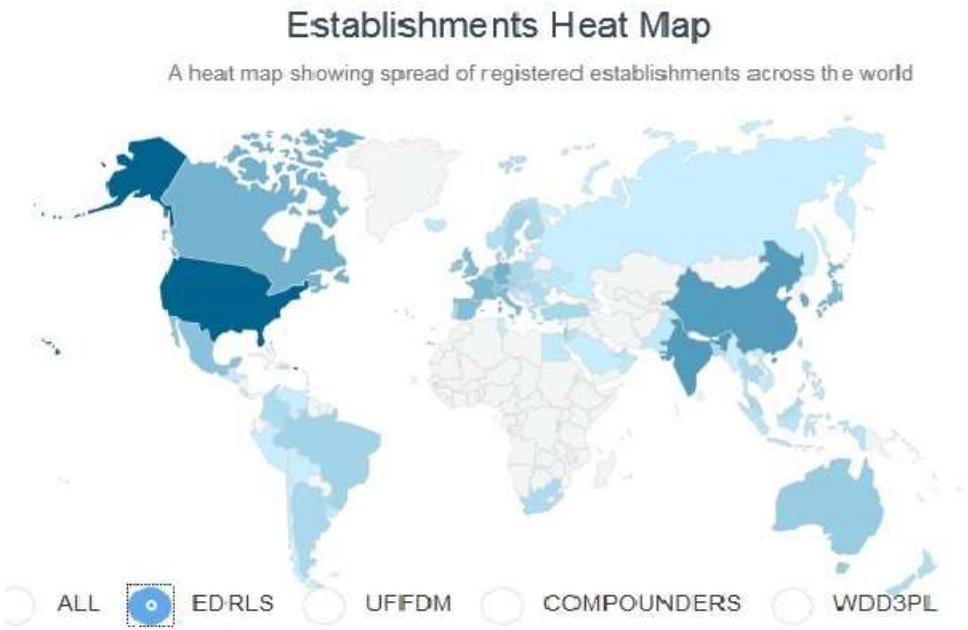
Registration and Listing Moving Forward

Future of DRLS Outreach

We're planning for the future of outreach and we need to hear from you!

- *New subject matter?*
- *New events to present attend and present?*
- *New professional associations to reach out to?*

In September 2019, DRLS travelled to People's Republic of China and was included in two industry GMP workshops, a bilateral meeting with the Chinese NMPA, and a lecture presentation to Peking University.



FDA U.S. FOOD & DRUG ADMINISTRATION

We hope you have a great day and a productive learning experience!